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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/087,217  | 03/04/2002  | Yong Yao             | 053735-5004-01      | 2158             |
| 9629  | 7590        | 01/06/2006           | EXAMINER            |                  |
| MORGAN LEWIS & BOCKIUS LLP<br>1111 PENNSYLVANIA AVENUE NW<br>WASHINGTON, DC 20004 |             |                      | ULM, JOHN D         |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |

1649

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                   |  |
|------------------------------|--------------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/087,217 | <b>Applicant(s)</b><br>YAO ET AL. |  |
|                              | <b>Examiner</b><br>John D. Ulm       | <b>Art Unit</b><br>1649           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-24, 26, 28-41, 43-45, 47, 49-62, 64-67, 69, 71, 73-82 and 103-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24 26 28-41 43-45 47 49-62 64-67 69 71 73-82 103-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71, 73 to 82 and 103 to 105 are pending in the instant application. Claims 22, 41, 43 and 64 have been amended and claims 103 to 105 have been added as requested by Applicant in the correspondence filed 13 October of 2005.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71, 73 to 82 and 103 to 105 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling for those reasons of record as applied to claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 in section 4 of the previous office action. As stated therein, these claims are not enabled because they omit a step or element that is critical or essential to the practice of the invention. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant claims are directed to a "method of detecting activity of a G protein-coupled receptor" by indirectly measuring the activity of a mutant GNC channel in a recombinant cell. As indicated in section 5 of the previous office action, because most, if not all, mammalian cells express a variety of endogenous G protein-coupled receptors an artisan can not attribute a measured channel activity to a specific G protein-coupled receptor, to the exclusion of all of the other G protein-coupled receptors expressed by a test cell, in the absence of a comparative step that employs a cell that is otherwise identical to the test

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cell except for the absence of receptor protein of interest. These claims are not enabled because the instant specification does not provide the guidance needed to practice the claimed method without employing such a comparative step. Applicant has provided a declaration by Xiao Li under 37 C.F.R. 1.132 asserting that "it was well known in the art that a negative control for GPCR expression is not always necessary, for instance where the host cell is known not to express relevant endogenous GPCRs". It is noted that the instant claims are not limited to host cells that are "known not to express relevant endogenous GPCRs" and that the instant specification fails to identify any such cells.

Applicant has again traversed this rejection on the premise that "the use of controls, such as the use of a negative control referred to by the Examiner, was well known by those of ordinary skill in the art at the time the present application was filed" and that "the use of a negative control for a G coupled protein receptor was known in the art". This position is further supported by the Xiao Li declaration, which states that "it is my expert opinion that any scientist working in the fields of molecular biology and protein interactions is well aware that it is routine to include appropriate controls in any scientific experiment" and that "it was well known at the time this application was filed that assays to detect activity of exogenous GPCRS may include the use of controls to account for endogenous GPCR activity, as would be commonly used in any biological assay measuring the activity of a transfected, exogenous protein". The fact that one of ordinary skill in the art of receptor biology would recognize the need for a comparative step in the claimed assay only supports the position that such a step is essential to that

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assay and therefore, must be included as a recited claim element. The rejection is maintained precisely because one of ordinary skill would recognize that such a control step is critical to the operability of the disclosed method and because the instant specification does not provide the guidance needed to practice that method without a control.

5) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 are vague and indefinite because there is no antecedent basis for the plurality of the limitation “detectable fluorescence signals from the dye”. Since the dye “produces a fluorescent signal” then one should be “measuring a detectable signal from the dye”.

5.2) Claims 39, 60 and 82 are confusing because the relationship between the “promiscuous G protein” and the “G protein-coupled receptor” recited therein is not specified. Applicant's reliance upon what is well known in the art does not resolve the ambiguous nature of the claims. Most, if not all, eukaryotic cells express a plurality of different G protein-coupled receptors and a plurality of different G proteins. A particular G protein-coupled receptor does not functionally interact with all of the G proteins present in the cell in which it is expressed. Therefore, these claims are ambiguous because it is unclear if the “promiscuous G protein” recited therein is required to functionally interact with “G protein-coupled receptor” recited therein.

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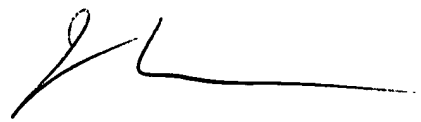
6) Applicant's arguments filed 13 October of 2005 have been fully considered but they are not persuasive for those reasons given above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



JOHN ULM  
PATENT EXAMINER  
GROUP 1800

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM  
PRIMARY EXAMINER  
1800